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10/771,897	02/04/2004	Narasimhan Gautam	15060-60	3893
69949 7590 09/10/2010 PATRICK W. RASCHE (15060) ARMSTRONG TEASDALE, LLP 7700 Forsyth Boulevard Suite 1800 St. Louis, MO 63105				
EXAMINER KAM, CHIH MIN				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
09/10/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

## Application No.

10/771,897

## Applicant(s)

GAUTAM ET AL.

## Examiner

CHIH-MIN KAM

## Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4, 7, 9, 11, 13-15, 17, 19, 20, 22-35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) 25-30, 32-34, 41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 35, 39 and 40 is/are rejected.
- 7) ☒ Claim(s) 7, 9, 11, 13-15, 17, 19, 20, 22-24, 31, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/29/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of the Claims***

1. Claims 4, 7, 9, 11, 13-15, 17, 19-20, 22-35 and 37-42 are pending.

Applicants' amendment filed June 29, 2010 is acknowledged. Applicants' response has been fully considered. Claim 7, 11, 13, 14, 17, 22-24, 31, 37, 39 and 40 have been amended. Claims 25-30, 32-34 and 41-42 are non-elected inventions and are withdrawn from consideration in this Office Action. Therefore, claims 4, 7, 9, 11, 13-15, 17, 19, 20, 22-24, 31, 35 and 37-40 are examined.

This application contains claims 25-30, 32-34 and 41-42 drawn to an invention nonelected with traverse in the reply filed on July 14, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Withdrawn Claim Rejections - 35 USC § 112***

2. The previous rejection of claims 7, 31 and 37 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 10-11 in the amendment filed June 29, 2010.

***Maintained Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 39 and 40 are indefinite because the claims lack essential steps in the claimed methods. For example, the claim merely recites the step of exposing a G protein biosensor cell containing a receptor and the G-protein biosensor of claim 4 to agonistic and antagonistic compounds without citing the steps of measuring FRET or BRET signal and analyzing the FRET or BRET profile. Thus, it is not clear how to classify the candidate therapeutic molecules as agonists, antagonists or inverse agonists.

*Response to Arguments*

Applicants indicate the specification provides explicit definitions for "agonist", "antagonist" and "inverse agonist" such that one skilled in the art would know the meaning of these terms by reading the specification. Moreover the specification describes the use of a known agonist to establish a baseline FRET profile for comparison with a candidate molecule and then classifying the candidate as an antagonist therapeutic drug molecule or not and as an inverse agonist. Thus, these rejections should be withdrawn (page 11 of the response).

Applicants' response has been considered. However, the arguments are not found persuasive because the claims do not recite the steps of measuring FRET or BRET signal and analyzing the FRET or BRET profile as argued above. Thus, the rejection is maintained.

***Maintained Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 4 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 45-46 of co-pending application 10/914,049 (based on the amendment filed 8/12/10). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4 and 35 in the instant application disclose a functional G protein biosensor comprising a mammalian  $\alpha$  subunit comprising a first amino acid sequence encoding at least one of a first fluorescent or a luminescent protein, and a mammalian  $\beta\gamma$  subunit complex, wherein the  $\beta$  subunit comprises a second amino acid sequence encoding at least one of a second fluorescent or luminescent protein and the  $\gamma$  subunit comprise a third amino acid sequence encoding at least one of a third fluorescent and or luminescent protein, wherein said first, second and third fluorescent or luminescent proteins are at least FRET or BRET capable. This is obvious variation in view of claims 1-3 and 45-46 of the co-pending application which disclose a functional biosensor comprising heterotrimeric G protein having alpha, translocatable beta and gamma subunits wherein both beta and gamma subunits are tagged with either a fluorescent protein or a luminescent protein, and wherein the beta and gamma subunits are tagged with the same fluorescent protein or luminescent protein. Both sets of claims cite directed to a functional

biosensor comprising heterotrimeric G protein having alpha, translocatable beta and gamma subunits, wherein both beta and gamma subunits are tagged with the same fluorescent protein or luminescent protein, which is FRET or BRET capable. Thus, claims 4 and 35 in present application and claims 1-3 and 45-46 in the co-pending application are obvious variations of a functional biosensor comprising heterotrimeric G protein having alpha, translocatable beta and gamma subunits wherein both beta and gamma subunits are tagged with the same fluorescent protein or luminescent protein, which is FRET or BRET capable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Response to Arguments*

Applicants indicate according to MPEP § 804 Part I.B. 1., "if a 'provisional' nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer." The instant application is the earlier filed application, filed on February 4, 2004, whereas co-pending application 10/914,049 was filed on August 7, 2004. Accordingly, Applicant respectfully requests upon overcoming the above § 112 rejections as indicated above (page 11 of the response).

Applicants' response has been considered. However, the arguments are not found persuasive because other ground of rejection is maintained, and the obviousness-type double patenting rejection is not the only rejection.

#### ***Claim Objections***

6. Claims 7, 9, 11, 13-15, 17, 19, 20, 22-24, 31, 37 and 38 are objected to because the claims are dependent from a rejected claim.

***Conclusion***

7. Claims 4, 35 and 39-40 are rejected; and claims 7, 9, 11, 13-15, 17, 19, 20, 22-24, 31, 37 and 38 are objected to.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

September 7, 2010